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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,992	08/10/2006	**Danielle Francisca Schuijffel**	1-2004.011 US	2404

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,992	SCHUIJFFEL ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-68* is/are pending in the application.

4a) Of the above claim(s) *55-61 and 66-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53,54 and 62-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 53, 54 and 62-65, drawn to isolated polypeptide. NOTE: If this Group is elected, Applicant must also elect a single polypeptide for examination, e.g., SEQ ID NO: X. This is a Restriction Requirement, not a species election.

Group II, claim(s) 55-61, 66 and 67, isolated polynucleotides. NOTE: If this Group is elected, Applicant must also elect a single polynucleotide for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

Group III, claim(s) 68, drawn to drawn to antibodies. . NOTE: If this Group is elected, Applicant must also elect a single antibody for examination, e.g., an antibody which binds to SEQ ID NO: X. This is a Restriction Requirement, not a species election.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions I-III comprise biologically, structurally and chemically distinct products. Additionally, there are patentably distinct products contained ***within*** each of these three groups, e.g., nucleotide sequences encoding different proteins (as well as proteins comprising different amino acid sequences/encoded by different nucleic acid sequences, and antibodies which bind completely different proteins) are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a species election requirement.

The polypeptide of group I and polynucleotide of group II represent different special technical features for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. Additionally, while a polypeptide of group I can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct. Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides

are not coextensive. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and II together.

The polypeptide of group I and the antibody of group III are different special technical features for the following reasons: While the inventions of both group I and group III are polypeptides, in this instance the polypeptide of group VI is a single chain molecule that functions as an enzyme, whereas the polypeptide of group I encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group III are structurally distinct molecules. Furthermore, searching the inventions of group I and group III would impose a serious search burden. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group II and the antibody of group III are patentably distinct for the following reasons. The antibody of group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group II. Therefore the antibody and polynucleotide represent distinct special technical features. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group III would impose a serious search burden since a search of the polynucleotide of group II is would not be used to determine the patentability of an antibody of group III, and vice-versa.

Accordingly, the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Bill Blackstone on 1/14/09 a provisional election was made without traverse to prosecute the invention of Group I, claims 53, 54 and 62-65; SEQ ID NO: 2 (which is encoded by SEQ ID NO: 1). Affirmation of this election must be made by applicant in replying to this Office action.

Claims 55-61 and 66-68 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Sequence Compliance

2. It is noted that Table 1 on page 27 of the instant specification recites nucleotide/amino acid sequences which are encompassed by the definitions for nucleotide sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). The M.P.E.P., Section 2422.02, 37 CFR 1.821(b) requires exclusive conformance, with regard to the manner in which the nucleotide/amino acid sequences are presented and described, with the sequence rules for all applications that include nucleotide sequences that fall within the definitions. It is unclear whether these sequences are recited in the Sequence Listing. The sequence identifiers obtained through conformance (paper submission and CRF/electronic) must be inserted into the body of the specification directly following the sequence. Additionally, Applicants are responsible for meeting compliance with any sequence the Examiner may have inadvertently missed.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R. 1.821-25. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. 1.821(g). Extensions of time may be obtained by filing

a petition accompanied by the extension fee under the provisions of 37 C.F.R. 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

Claim Rejections - 35 USC § 112-2nd paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 53, 54 and 62-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 is vague and indefinite because it the mere recitation of a name, i.e., "isolated *Orinthobacterium rhinotracheale* protein or isolated immunogenic fragment thereof…", to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. There are several proteins from *O.rhinotracheaele* and it is unclear which protein is being claimed. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. The mere recitation of a name does not adequately define the claimed protein. Additionally, it is unclear what the terms 'protective homologous immune response' and "protective cross-reactive immune response' are in reference to. Are these terms in reference to the protein, to the Genus, to the species, to the strain, etc.? Claims 53, 54 and 62 are also vague and indefinite due to the term 'immunogenic fragment' as it is unclear what structure is encompassed by these claims. The

specification does not adequately define these structures. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 54 is vague and confusing because it recites that the 'protein or immunogenic fragment of claim 53 is selected from the group consisting of SEQ ID NO: 2, etc.. SEQ ID NO: 2 is the amino acid sequence of the protein named 'Or01' having a molecular weight of 59.8 kD and is not an 'immunogenic fragment'. Accordingly, the claim does not properly recite 'fragments thereof', e.g., from SEQ ID NO: 2, and it is unclear what other fragments are being claimed.

Claim 62 is also vague and indefinite due to the phrase 'for combating *Orinthobacterium rhinotracheale* infection'. What is encompassed by this phrase, e.g., a reduction of specific symptoms, a reduction of viable microorganisms, induction of a specific immune response, etc.? The metes and bounds of the invention cannot be understood. Clarification and correction is requested.

Claim 64 is vague and indefinite due to the phrase 'genetic information encoding said antigen". What is this 'genetic information'? Is this nucleic acid or something else? The metes and bounds of the claim cannot be understood. Clarification is requested.

Claim Objections

5. Claims 53, 54 and 62-65 are objected to because of the following informalities: the claims contain non-elected SEQ ID Nos. which should be removed from the claim.

In claim 64, the first word of the claim, e.g., the, should be capitalized.

Appropriate correction is required.

Claim Rejections - 35 USC § 112-Enablement

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 53, 54 and 62-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to an isolated isolated *Orinthobacterium rhinotracheale* protein or isolated immunogenic fragment thereofs, and more specifically, in claim 54 the polypeptide comprising SEQ ID NO: 2 and fragments thereof. Vaccines comprising said protein or fragments for 'combating *Orinthobacterium rhinotracheale* infection". The claims are not enabled for the scope of this invention.

The specification does enable 'an isolated Orinthobacterium rhinotracheale protein comprising the amino acid sequence set forth in SEQ ID NO: 2' and 'an isolated Orinthobacterium rhinotracheale protein which is encoded by the isolated nucleic acid sequence set forth in SEQ ID NO: 1. However, the specification does not enable immunogenic fragments or vaccines comprising the claimed polypeptide or its fragments. When considering a bacterial antigen as a vaccine candidate, three major

considerations must be raised (1) the antigen must be conserved among strains of the bacterial species whose disease one wishes to prevent; (2) it must generate protective antibody such that the antibody to the antigen prevents disease; and (3) it must be a good immunogen such that protective antibodies are elicited in the population at risk and that these antibodies persist for sufficient time to provide protection throughout the risk period (Murphy et al. Pediatr. Infect. Dis. J. 1989. 8: S66-S68). Even when an antigen meets these three considerations, further testing often indicates that the antigen will not be effective as a vaccine. For example, Murphy et al. Pediatr. Infect. Dis. J. 1989. 8: S66-S68, teach that P6 is an important vaccine candidate based on these considerations, but Yamanaka et al (J. Pediatrics. 1993. 122(2): 212-218) later demonstrated that the population at most risk did recognize P6 as an antigen. The instant specification fails to demonstrate that the claimed protein, Or01, which has a molecular weight of 59.8 kD and is encoded by the nucleic acid having the sequence set forth in SEQ ID NO: 1 (much less any of its fragments) meets any of the three considerations known in the art to be important when considering a bacterial antigen as a vaccine candidate. While it is most certain the full-length polypeptide could raise an immune response, the specification does not teach a protective immune response such as is required by a 'vaccine' claim. Additionally, claim 53 does not even recite a specific protein, but is drawn to *any* protein from *Orinthobacterium rhinotracheale*. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519,

536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." The specification also fails to teach or enable any specific fragments from the claimed protein, particularly ones which would provide a protective effect, e.g., vaccine. The location of protective epitopes have not been identified. Often times it takes more than one epitope to provide a protective effect. As stated above, selective point mutation to one key antigen could eliminate the ability of an antibody to recognize this altered antigen. Without specific guidance from the specification, it would take undue experimentation for those skilled in the art to make and/or use the claimed invention.

Protection studies to assess the cross-protective capacity of some subunit vaccines are described in Example 4 of the instant specification but they are performed on a combi vaccine which comprise all 5 proteins and individual vaccine Or77, neither of which are claimed. The results from these experiments do not correlate to success using the different protein/vaccine which is claimed. The specification at page 24, lines 15-17 does teach that birds vaccinated with individual Oro1 vaccine did show protein specific reactivity, but this does not correlate to a 'vaccine'. It is taught that birds vaccinated with a vaccine containing all 8 proteins showed almost complete protection

compared to a control group. Again, this does not extrapolate to use of the single protein which is claimed.

Specification

8. The disclosure is objected to because of the following informalities: The description of Figure 3 on page 26 fails to recite 'Figures 3A-3F' as is shown in the actual Figure.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a

nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are

solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if

an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 53, 54 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Cao et al (US 20030233675 A1).

Cao teach isolated immunogenic fragments from SEQ ID NO: 2. They teach an isolated polypeptide with an overall similarity of 56.2% to SEQ ID NO: 2. See sequence alignment under 'SCORE' in Public PAIR. Fragments of at least 80% identity to the full-length sequences are taught and see column 5, paragraph [0058]- end of column 6, which teaches fragments of at least 50 amino acids in length and variants and homologs of 35-95% or greater. The phrase "induce both a protective homologous immune response and a protective cross-reactive immune response", as well as "vaccine" are intended uses only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the

prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "pharmaceutically acceptable carrier" reads on water and therefore would be inherent in the preparation of the polypeptides. The structure recited in Cao is structurally identical to the claimed fragments and therefore would possess the same functional activities.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

1/27/09